Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DOUGLAS H. WEST

Appeal No. 2000-1909
Application No. 08/790,528

ON BRIEF

Before ADAMS, MILLS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-20. Claims 1 and 10 are representative of the claims on appeal, and read as follows:

1. A masticatory for treating the multifactorial etiology of gastroesophageal reflux disease comprising: a chewing-gum base, an acid neutralizing agent, an anti-gas agent, and an acid production inhibitor.

10. A chewing-gum composition for treatment of the multifactorial etiology of gastroesophageal reflux disease comprising: a chewing-gum

integral with a chewable tablet, the chewable tablet including an acid neutralizing agent, an anti-gas agent, and an acid production inhibitor.

The examiner relies upon the following references:

Beringer et al. (Beringer)	4,139,589	Feb. 13, 1979
Cherukuri et al. (Cherukuri)	4,971,787	Nov. 20, 1990
Singer et al. (Singer)	5,294,433	Mar. 15, 1994
Upson	WO92/17161	Oct. 15, 1992
Caldwell	WO95/05173	Feb. 23, 1995
France (European Patent)	0 349 103	Jan. 03, 1990
Gottwald (European Patent)	0 322 048	June 28, 1989

FDA Consumer (1995), p. 759, listing of product labeled "Tempo"

Drug Facts and Comparisons, (50th ed. 1996), Chapter 7, "Gastrointestinal Drugs" pp. 1823-1891

Claims 1-9 and 19 stand rejected as obvious over the combination of "Tempo" as set forth in FDA Consumer and Singer. Claims 10-20 stand rejected as obvious over the combination of Caldwell, Gottwald, France or Upson and Drug Facts and Comparisons, Beringer and Cherukuri. After careful review of the record and consideration of the issues before us, we reverse both rejections.

DISCUSSION

Claims 1-9 and 19 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of "Tempo" as set forth in FDA Consumer and Singer. The rejection is set forth in relevant part below.

> FDA Consumer, 1995 sets forth a product marketed under the trade name "Tempo" which comprises calcium carbonate, an antacid, and simethicone, an anti-flatulent, in a chewable matrix for the treatment of gastroesophageal disorders. Singer [ ] discloses H-2 antagonists in a chewing gum base. . . . Singer indicates that H-2 antagonists are well known in the art for the treatment for esophagitis through the inhibition of acid production. . . . Singer

> discloses the H-2 antagonists can be incorporated into a chewing gum matrix and are released from said matrix. The antacid and anti-flatulent are ingredients well known and often used in the treatment of acid reflux or GERD, as set forth previously. H-2 antagonists are also well known for use in the treatment of acid reflux or GERD. The court has determined that the combination of two or more ingredients known in the art for the same uses is obvious, and unpatentable. (In re Kerkhoven 205 USPQ 1069 (CCPA 1980)) which states: "It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form [a] [*sic*] third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art . . .") It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the acid production inhibitor of Singer with the antacids and antiflatulents of composition marketed as Tempo, as it would lead to a longer term inhibition of acid production, in combination with the quick acid relief provided by the antacids and the anti-flatulent.

Examiner's Answer, pages 4-5.

Appellant argues that there is no motivation to combine Singer with the composition marketed as Tempo. Appellant asserts that while Singer teaches the use of H-2 antagonists in a chewing gum matrix for the treatment of gingivitis, Singer teaches the use of the chewing gum matrix as a topical carrier that is expectorated rather than be swallowed. Thus, appellant argues there is no motivation to combine a product that is chewed and not swallowed, i.e., the chewing gum of Singer, with a product that is to be swallowed, i.e.. the Tempo composition. See Appeal Brief, pages 4-6.

The burden is on the examiner to set forth a prima facie case of obviousness. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). With respect to an obviousness rejection based on a combination of references, as the court has stated, "virtually all [inventions] are

combinations of old elements." Environmental Designs, Ltd. V. Union Oil Co., 713 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); see also Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1579-80, 219 U.S.P.Q. (BNA) 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore, an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. The United States Court of Appeals for the Federal Circuit, our reviewing court, however, has stated that "the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references." Ecolochem, Inc. v. Southern California Edison Co., 227 F.3d 1361, 1371, 56 USPQ2d 1065, 1073 (Fed. Cir. 2000).

In this situation, the rejection fails to show that one of ordinary skill in the art would have been motivated to incorporate an acid neutralizing agent, an anti-gas agent, and an acid production inhibitor in a chewing gum base. Singer teaches the incorporation of an acid-production inhibitor, i.e., an H-2 receptor antagonist, in a chewing gum to deliver the antagonist to the oral cavity for the treatment of gingivitis. Singer, however, provides no motivation to add the acid neutralizing base and an anti-gas agent to the chewing gum matrix because Singer only teaches the use of the chewing gum to deliver an active agent to the oral cavity for the treatment of gingivitis, and does not teach or suggest its use for the delivery of active agents for the treatment of gastroesophageal reflux

disease. While FDA Consumer teaches the combination of an acid neutralizing agent and an anti-gas agent in a chewable tablet for the treatment of gastroesophageal reflux disease, it also provides no teaching or suggestion for incorporating the active agents into a chewing gum matrix. Thus, the examiner has failed to set forth a prima facie case of obviousness.

Claims 10-20 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Caldwell, Gottwald, France or Upson and Drug Facts and Comparisons, Beringer and Cherukuri.

According to the rejection, Caldwell, Gottwald, France and Upson each teach a chewable tablet comprising an H-2 receptor antagonist, i.e., an acid production inhibitor, and an acid neutralizing agent. Drug Facts and Comparisons is relied upon for teaching chewable tablets comprising a hydroxide or carbonate antacid, i.e., an acid neutralizing agent, and simethicone, i.e., an anti-gas agent. The answer reasons that

> [a]s both acid-production inhibitors in combination with antacids and antiflatulents in combination with antacids have been shown to be well known for use in chewable tablets for the treatment of gastroesophageal disorders, it is expected, absent unexpected results, that a tablet comprising all three ingredients would also be useful in the treatment of gastroesophageal disorders. The court has determined that the combination of two or more ingredients known in the art for the same uses is obvious, and unpatentable. (In re Kerkhoven 205 USPQ 1069 (CCPA 1980)) which states: "It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form [a] [*sic*] third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art . . ."

Examiner's Answer, pages 6-7.

The rejection relies upon Beringer for teaching "the standard methods of making tablets that are encased by gum, as well as methods of making gum encased by a chewable tablet for the administration of a pharmaceutically active agent." Id. at 7. Cherukuri is cited for teaching chewing gums that incorporate antacids, as well as disclosing "the many sweeteners, and flavoring agents useful in the production of a medicated gum." Id. The rejection concludes that

> [i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have added an antiflatulent to the chewable tablets of Caldwell, Gottwald, France or Upson, as both the antiflatulents and the combinations thereof with antacids and acid production inhibitors in a chewable form were well known in the art at the time the invention was made for the treatment of gastroesophageal disorders, as listed by Drug Facts and Comparisons. It would have further been obvious to have added an integral chewing gum through the methods of Beringer or Cherukuri, as such multi zone delivery compositions were well known in the art and they allowed the incorporation of different pharmaceuticals.

Id. at 7-8.

Appellant argues that the references relied upon by the examiner do not provide any motivation to provide a chewable tablet containing an antacid, an anti-gas agent and a H-2 receptor antagonist integral with a chewing gum matrix. We agree.

The rejection states that it would have been obvious "to have added an integral chewing gum through the methods of Beringer or Cherukuri, as such multi zone delivery compositions were well known in the art and they allowed the incorporation of different pharmaceuticals." Examiner's Answer, pages 7-8. While it may have been known that pharmaceuticals may be incorporated into a multi-zone delivery device, the rejection does not address why the ordinary artisan would have been motivated to place all of the active ingredients in a chewable tablet, and then add a chewing-gum integral with the chewable tablet. Specifically, if all of the active ingredients were placed in a chewable tablet, the rejection does not address why one of ordinary skill in the art at the time the invention was made would have been motivated to add a chewing-gum integral with the chewable tablet, which already contains all of the active ingredients. See In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432 (Fed. Cir. 2002) (in reviewing an obviousness rejection, the court noted that "conclusory statements" as to teaching, suggestion or motivation to arrive at the claimed invention "do not adequately address the issue.").

Moreover, the examiner has ignored certain teachings of the prior art references that would lead one away from the claimed invention. Obviousness is not based on isolated teachings in the art, but is determined in view of the sum of all of the relevant teachings in the art. See In re Kuderna, 426 F.2d 385, 389, 165 USPQ 575, 578 (CCPA 1970); see also In re Shuman, 361 F.2d 1008, 1012, 150 USPQ 54, 57 (CCPA 1966). For example, Caldwell teaches that the use of an effervescent tablet to deliver a H-2 antagonist reduces the bioavailability of

the active ingredient. See Caldwell, page 2, first full paragraph. Gottwald teaches that H-2 antagonists, such as cimetidine, have a very bitter taste, and thus they are usually administered as a tablet. Moreover, Gottwald also teaches that a tablet containing the antagonist should release the active ingredient rapidly and completely upon reaching the stomach. See Gottwald, page 3, lines 5-23. In addition, France teaches that H-2 receptor antagonists are bitter, and thus have palatability problems. See France, page 2. These disclosures thus teach away from placing an H-2 receptor antagonist integral with a chewing gum matrix because of the problems of bioavailability of the antagonist, as well as its bitter taste, which, as noted by France, would reduce patient compliance.

CONCLUSION

As the rejections under 35 U.S.C. § 103(a) fail to set forth a prima facie case of obviousness, they are reversed.

REVERSED

Donald E. Adams Administrative Patent Judge	))))) BOARD OF PATENT
Demetra J. Mills Administrative Patent Judge	)) APPEALS AND)) INTERFERENCES
Lora M. Greeen Administrative Patent Judge	))

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